DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

1/23/98

D1055B

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-15

December 24, 1997

Ms. Jane Blanks
President
America's Best Nutrition
114 Palmetto Street
Suite 9
Destin, Florida 32541

Dear Ms. Blanks:

This letter is written in reference to your firm's marketing and distribution of "Trim-Phen". Your product is labeled as an alternative to the prescription drug, phentermine. This prescription drug is intended to treat obesity. Labeling your product as an alternative to phentermine represents it as intended for the same use as phentermine. Thus, you are representing "Trim-Phen" as a treatment for obesity. In this regard, "Trim-Phen" is a drug as defined in Section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

"Trim-Phen" is a "new drug" under Section 201(p) of the Act based on: 1) the trade name, "Trim-Phen", and the statement "Much attention has recently been focused on the harmful 'side effects' of pharmaceutical weight loss drugs. Trim-Phen is an all natural 'alternative' for safe and effective results with none of the side effects of these drugs," and 2) the lack of any evidence that these products are generally recognized as safe and effective for the treatment of obesity.

Since this drug is a "new drug", it may not be legally marketed in the United States without an approved new drug application [Section 505(a) of the Act). "Trim-Phen" is also misbranded because its labeling fails to bear adequate directions for use [Section 502(f)(1) of the Act) and the labeling is false and misleading since it suggests that the product is recognized as safe and effective for the intended use [Section 502(a) of the Act] and this is not the case. Labeling is not limited to the immediate product containers, but includes all promotional literature which you distribute in connection with the product.

This letter is not intended to be an all inclusive review of all labeling and products that your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Martin E. Katz, Compliance Officer, U. S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, ext. 262.

Sincerely,

Michael A. Chappell
Acting Director
Florida District